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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,922	02/09/2004	Kristopher Henry Vietmeier	S63.2B-11269-US01	8838

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/774,922

Applicant(s) ^{NT}VIETMEIER, KRISTOPHER
HENRY

Examiner

Jermie Cozart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/06 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no antecedent basis for "wherein the shape of the receptacle is maintained" as presented in claims 40 and 57, and also there is no antecedent basis for "wherein the shape of the receptacle is maintained during the transforming step" as presented in claims 41 and 58. Appropriate correction is required.

Claim Objections

3. Claim 51 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 50. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 40-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically in claims 40 and 57, the specification does not state that the shape of the receptacle is maintained during the enlarging step, when as mentioned as previously in claims 40 and 57 the shape of the receptacle is enlarged. Also with respect to claims 41 and 58, the specification does not mention the shape of the receptacle being maintained during the transforming step. The receptacle has to return to its original configuration in order to retain the marker therein, therefore at least a portion of the receptacle does not maintain its shape. The specification discloses a portion/confines of the receptacle being enlarged, however, the specification is silent as to whether or not the remaining portion of the receptacle is either enlarged or not enlarged.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 40-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. In claims 40 and 57, at respective steps b) and c), it is unclear as to how the shape of the receptacle is maintained during the enlarging step when the shape of the receptacle is enlarged while the shape memory material is in the martensitic phase. In claims 41 and 58, it is unclear as to how the shape of the receptacle is maintained during the transforming step, when the receptacle has to return to its original shape in order to retain the marker therein. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 40-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackiewicz et al. (US 2005/0060025 A1).

Mackiewicz discloses a precursor (34) for an implantable medical device (i.e. stent) having at least a portion of the precursor (34) made of a shape memory material (i.e. nitinol), the shape memory material having a receptacle (38) for receiving a marker (36) therein, the shape memory material having an austenitic and a martensitic phase. The receptacle (38) has a shape and is enlarged while the shape memory material is in the martensitic phase, and a marker (36) is inserted in the receptacle (38) while the shape memory material is in the martensitic phase, and thereafter the precursor is transformed to the austenitic phase. The precursor is a medical device one example

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being a stent precursor which encompasses a stent-graft precursor. The precursor having a plurality of receptacles (38) for receiving a plurality of markers (36).

Mackiewicz discloses heat being applied to the plurality of receptacles (38) prior to transforming the precursor to the austenitic phase. The precursor is post-processed to form an implantable device (i.e. stent or stent-graft) suitable for implantation in the body, wherein the post-processing includes the step of polishing the precursor. The stent has a first end and a second end, wherein the receptacle (38) is positioned (figs. 6-7) at the first end of the stent. The marker (36) is radiopaque. The marker (36) does not comprise material (paragraph 0035) in common with the shape memory material of the implantable medical device and wherein the marker (36) is in direct contact with the shape memory material of the implantable device after the precursor is transformed to the austenitic phase. *See paragraphs [0021]-[0054], and figures 1-7 for further clarification.*

Mackiewicz, however, does not disclose the following: the shape of the receptacle being maintained during the enlarging step; the shape of the receptacle being maintained during the transforming step; the receptacle being positioned between the first end of the stent and the second end of the stent; the implantable medical device being formed prior to the receptacle being enlarged; the implantable medical device and the receptacle being made from different materials; the shape memory material being polymeric; or the shape of the receptacle being substantially circular.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to maintain the shape of the receptacle during the enlarging step and transforming step, to position the

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receptacle between the first end and second end of the stent, to form the implantable medical device prior to the receptacle being enlarged, to make the implantable medical device and the receptacle from different materials, to make the shape memory material polymeric, and to make the shape of the receptacle substantially circular because Applicant has not disclosed that maintaining the shape of the receptacle during the enlarging or transforming steps, positioning the receptacle between the first end and second end of the stent, forming the implantable medical device prior to the receptacle being enlarged, making the implantable medical device and the receptacle from different materials, making the shape memory material polymeric, or forming the shape of the receptacle as substantially circular provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with that which is taught by Mackiewicz because the markers are effectively held within the receptacles of the implantable device and the implantable device is easily locatable when deployed.

Therefore, it would have been an obvious matter of design choice to modify Mackiewicz to obtain the invention as specified in claim 40-80.

Response to Amendment

10. The Declaration under 37 CFR 1.132 filed 9/25/06 is insufficient to overcome the rejection of claims 1-39 based upon Mackiewicz et al. as set forth in the last Office action because:

The Declaration refers to claims 1 and 17 which have been canceled by the present amendment. The Declaration fails to provide supporting evidence (i.e. charts, graphs, tables) detailing the benefits of receptacles formed according the present method versus those receptacles formed according to Mackiewicz. The Declaration fails to show any evidence of non-uniform strain resulting from the receptacles of Mackiewicz or any evidence of uniform strain resulting from the evidence of the present invention. The Declaration fails to show why maintaining the shape of the receptacle during the enlarging and transforming steps are not a matter of obvious design choice. The Declaration fails to show any evidence of unexpected results, long felt need, or commercial success with respect to the claimed invention.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.


Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JERMIE E. COZART
PRIMARY EXAMINER

December 11, 2006